Regulation History

Type Of Regulation: Sales and Use Tax
Regulations: 1591
Title: *Medicines and Medical Devices*
Preparation: Lynn Whitaker/Peter Horton
Legal Contact: Randy Ferris/Trecia Nienow

In September 2005, the Board was petitioned to amend the definition of "medicines" in Regulation 1591, subdivision (a)(9). Revenue and Taxation Code section (Section) 6369, interpreted and implemented by Regulation 1591, provides that sales or other transfers of medicines as defined in the statute are not subject to tax if they are sold or otherwise transferred pursuant to the requirements set forth in the statute. In Section 6369, subdivision (b), the Legislature has provided that the term "medicines" means "any substance or preparation ***intended*** for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease and commonly recognized as a substance or preparation intended for that use [emphasis supplied]." Thus, the intent (or professional judgment) of the qualified person (e.g., doctors) ultimately prescribing or furnishing the substance or preparation for treatment is an essential element to the statutory definition of "medicines." Assuming all the other requirements for exemption are met, the Legislature has set up a statutory scheme where the professional judgment of doctors is deferred to regarding whether they have prescribed or furnished the substance or preparation for use in the treatment of a disease or for some other purpose (i.e., for a purpose that is wholly unrelated to the treatment of a medical condition). The same deference to the professional judgment of doctors and other qualified persons is also required for devices and articles prescribed or furnished under subdivision (c) of Section 6369.

The Board has concluded that revisions are needed because Board auditors were erroneously assessing tax on nontaxable sales of prescription drugs, devices and articles approved by the U.S. Food and Drug Administration (FDA) for the treatment of medical conditions. Confusion on the correct application of tax arose when such FDA-approved products could be used either to treat a medical condition or for purely cosmetic purposes. The Board has concluded that to make the determination as to whether or not a product is sold for an exempt purpose, when the product is susceptible to a dual use, would require auditors to investigate unnecessarily doctors' practices and to examine patient records, thus violating the doctor-patient privilege.

The amendments clarify that except where taxable for all purposes as provided in Regulation 1591, subdivision (c), "medicines" include any product approved by the FDA to treat medical conditions. Regulation 1591, subdivision (c), provides that except as otherwise provided in subdivision (b) of 1591, certain items (including various medical devices and articles) are specifically excluded from the definition of "medicines."

History of Amendments

April 18, 2006:	Public hearing.
April 17, 2006:	45-Day public comment period ends.
March 4, 2006:	45-Day public comment period begins.
March 3, 2006:	Notice of public hearing published in California Regulatory Notice Register, Register 2006, No. 9-Z, e-mailed and US mail to interested parties.
January 31, 2006:	Business Taxes Committee Meeting, (Vote 5-0)
November 30, 2005:	Interested Parties Meeting
November 1, 2005:	Topic Placed on Business Taxes Committee Calendar

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Sponsor:	Petitioners: California Society of Dermatology and Dermatologic Surgery, California Society of Plastic Surgery, California Academy of Ophthalmology, California Medical Association
Support:	Petitioners

Forty-three letters received from various interested parties

Oppose:	None expressed.